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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
RANGREJ, SHEETAL	

ART UNIT	PAPER NUMBER
3686	

MAIL DATE	DELIVERY MODE
09/01/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/864,891	NG ET AL.	
	Examiner	Art Unit	
	SHEETAL R. RANGREJ	3686	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 May 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8-28 and 30-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *8-28 and 30-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Prosecution History Summary

1. Claims 1-7 and 29 are cancelled.

2. Claims 8-12, 14, 23-28, 30-35, 37, and 39-54 are amended.

3. Claims 8-28 and 30-54 are pending.

Continued Examination Under 37 CFR 1.114

4. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 05/22/2009 has been entered.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. Claims 8-28 and 30-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fletcher-Haynes et al. (U.S. Publication No. 2001/0034614) in view of Wojocik et al. (U.S. Patent No. 5,666,493).

7. As per claim 8, Fletcher discloses a system for managing an inventory of blood component collection kits and for preventing the use of quarantined blood component collection

kits, the system comprising:

(1) a blood component collection instrument for collecting a blood component from a blood component donor in a blood component collection kit **(Fletcher: par. [0056] and [0125]**; Examiner notes, in particular, that Fletcher teaches that the blood/blood components are collected into "bags" via "tubing sets" (i.e., "blood component soft goods" or "the container or kit which holds the collected blood component," as defined by Applicant on pg. 14 of Applicant's response filed 6/30/2006)**)**;

(2) a system computer being operably connected to the blood component collection instrument **(Fletcher: par. [0057])**, the system computer running a blood component collection application for at least a portion of a blood component collection process **(Fletcher: par. [0057])**, wherein the system computer is in data communication with a system database having a blood component collection kit inventory **(Fletcher: par. [0056], [0063], and [0195])**; and

(3) an interface being operably connected to the system computer **(Fletcher: par. [0057])**.

Examiner notes that Fletcher teaches the use of a multitude of graphical user interfaces (GUIs) having numerous fields for a indicating a variety of things including blood component inventory levels, machine identification numbers, blood collection bag identification numbers, blood component collection volumes, tubing set identification numbers, etc. **(Fletcher: Figs. 2A-6M)**. As such, Examiner considers GUIs having various inventory indication fields to be notoriously well known.

Fletcher, however fails to expressly disclose a system for managing an inventory of blood component collection kits and for preventing the use of quarantined blood component collection kits, the system comprising:

(4) a system computer, wherein the system computer is in data communication with a system database having a blood component collection kit inventory and quarantine information relative thereto, and said system computer processes said inventory and quarantine information prior to use of the blood component kit; and

(5) the interface having a quarantine field for indicating that at least a portion of the blood component collection kit inventory is quarantined based on the processing of the inventory and quarantined information prior to use of the blood component kit.

Nevertheless, these features are old and well known in the art, as evidenced by Wojocik. In particular, Wojocik discloses a system for managing inventory of blood component collection soft goods and for preventing the use of quarantined soft goods, the system comprising:

(4) a system computer, wherein the system computer is in data communication with a system database having a blood component collection kit inventory and quarantine information relative thereto, and said system computer processes said inventory and quarantine information prior to use of the blood component kit **(Wojocik: col. 16, 53-60)**; and (A reference in a field different from that of applicant's endeavor may be reasonably pertinent if it is one which, because of the matter with which it deals, logically would have commended itself to an inventor's attention in considering his or her invention as a whole [MPEP 2141.01]. Prior art of record provides common essential elements, though the prior art applied does not deal with healthcare goods but rather goods in general; furthermore it solves the pertinent problem).

(5) the interface having a quarantine field for indicating that at least a portion of the blood component collection kit inventory is quarantined based on the processing of the inventory and quarantined information prior to use of the blood component kit **(Wojocik: col. 16, 53-60)**.

One of ordinary skill would have found it obvious at the time of the invention to combine the teachings of Fletcher and Wojocik with the motivation of providing a quality control check **(Wojocik: col. 19, 4-13)**.

8. As per claim 9, Fletcher discloses the system of claim 8, wherein the interface communicates to the system database an identification of the blood component collection kits **(Fletcher: par. [0022], [0083], [0125], and [0162])** (Examiner notes also that Fletcher teaches the use of various GUI comment fields whereby a user of the system could indicate that a particular soft good is unsuitable (i.e., quarantined)).

Fletcher, however, fails to expressly disclose the system of claim 8, wherein the interface communicates to the system database an identification of the [quarantined] blood component collection kits.

Nevertheless, this feature, as aforementioned, is old and well known, as evidenced by Wojocik. In particular, Wojocik discloses the system of claim 8, wherein the interface communicates to the system database an identification of the quarantined blood component collection kits **Wojocik: col. 16, 53-60)**.

One of ordinary skill would have found it obvious at the time of the invention to combine the teachings of Fletcher and Wojocik with the motivation of providing a quality control check **(Wojocik: col. 19, 4-13)**.

9. As per claim 10, Fletcher discloses the system claim 8, wherein the blood component collection kit **(Fletcher: par. [0022], [0071], [0192], and [0315]**) (Examiner considers a barcode, needle, receptacle bag, tubing set, and blood containers, among other soft goods to read on "blood component collection kit.").

Examiner has noted insofar as claim 10 recites "includes a blood component collection solution, or a blood component collection transfer pack," a blood component collection kit has been recited.

10. As per claim 11, Fletcher discloses the system of claim 8, wherein the interface further comprises a reader being operably connected to the system computer for receiving an operator identifier and transmitting the operator identifier to the system computer, and for receiving separate input of a blood component collection kit identifier and transmitting the blood component collection kit identifier to the system database **(Fletcher: par. [0022], [0059], [0071], [0079], [0083], and [0125])**.

In short, Fletcher teaches a system replete with a myriad of identifiers (e.g., operator identifiers, instrument/device/identifiers, donor identifiers, soft good identifiers, inventory identifiers, etc.) being received and transmitted by the system computer in conjunction with an array of peripheral devices (e.g., barcode readers, scanners, cameras, etc.) **(Fletcher: par. [0022], [0059], [0071], [0079], [0083], and [0125])**.

11. As per claim 12, Fletcher discloses the system of claim 11, wherein the operator identifier and a blood component collection kit identifier are received from a location proximate the blood component collection instrument **(Fletcher: par. [0022], [0058], [0059], [0079], [0083], and [0125])**.

12. As per claim 13, Fletcher discloses the system claim 8, wherein the system database is integral with the system computer **(Fletcher: par. [0057] and [0058])**.

In fact, Fletcher teaches multiple system configurations including, but not limited to, one where the system database can be included therein (i.e., integral within the computer), one where

the system database is positioned in close proximity with the system computer (i.e., integral to the computer system), and one where the system database is located remotely (i.e., integral to the computer system network) **(Fletcher: par. [0057] and [0058])**.

13. As per claim 14, Fletcher discloses the system of claim 8, further comprising a blood component collection donor identifier corresponding to a blood component donor, wherein the blood component collection donor identifier is transmittable to the system computer for storing the blood component collection donor identifier in the memory and for associating the blood component collection donor identifier with at least one of the blood component collection kit identifier and the blood collection instrument identifier **(Fletcher: par. [0022], [0068], [0124], [0125], [0142] and [0159]; Fig. 2A-6M)**.

14. As per claim 15, Fletcher discloses the system of claim 8, wherein the blood component collection instrument further comprises a blood component collection instrument identifier **(Fletcher: par. [0159]; Fig. 4A)**.

15. As per claim 16, Fletcher discloses the system claim 8, wherein the interface utilizes radio frequency to transmit to the system computer **(Fletcher: par. [0059])**.

In fact, Fletcher teaches an open computer system architecture that may leverage a broad assortment of interface transmission means including cable, satellite, and energy wave communication, among other transmission means **(Fletcher: par. [0059])**.

16. As per claim 17, Fletcher discloses the system of claim 8, further comprising:

(a) a system communication conduit for operably connecting the system computer to the blood component collection instrument **(Fletcher: par. [0012])**; and,

(b) a system communication protocol for facilitating communication on the communication

conduit between the system computer and the blood component collection instrument **(Fletcher: par. [0030])**.

17. As per claim 18, Fletcher discloses the system of claim 17, wherein the system communication protocol is Ethernet **(Fletcher: par. [0030])**.

18. As per claim 19, Fletcher discloses the system of claim 17, wherein the system communication protocol is TCP/IP **(Fletcher: par. [0030] and [0194])**.

19. As per claim 20, Fletcher discloses the system of claim 17, further comprising:

(a) a network server being operably connected to the system computer via a network communication conduit **(Fletcher: par. [0012] and [0065])**; and

(b) a web interface being operably connected to the system computer for facilitating access to the blood component collection process, wherein the interface receives data from the system computer **(Fletcher: par. [0033] and [0194])**.

20. As per claim 21, Fletcher discloses the system of claim 20, further comprising a web server being operably connected to the system computer and operably responsive to a web browser wherein the information stored in the system computer can be accessed **(Fletcher: par. [0033] and [0194])**.

21. As per claim 22, Fletcher discloses the system of claim 20, wherein the interface comprises a reader having at least one of a touch pad **(Fletcher: par. [0057])**.

Examiner has noted insofar as claim 22 recites "at least one of a touch pad, a keypad, an optical scanner, and a magnetic scanner" a touch pad has been recited.

22. As per claim 23, Fletcher discloses the system of claim 8, wherein the system database further comprises separate inventory data for each of a plurality of different types of blood component collection kits **(Fletcher: par. [0011] and [0166]; Figs. 2A-6M)**.

Examiner notes that Fletcher specifically teaches capturing, tracking, editing, printing, manipulating, measuring, modifying, calculating, transmitting, and receiving various soft goods (e.g., various blood component solutions, such as plasma, red blood cells, etc.; blood collection kits including needles, blood collection bags, etc.) inventory data pertinent to the blood collection process **(Fletcher: par. [0011] and [0166]; Figs. 2A- 6M)**.

23. As per claim 24, Fletcher discloses the system of claim 23, wherein the plurality of different types of blood component collection kits **(Fletcher: par. [0022], [0071], [0192], and [0315])** (Examiner considers a barcode, needle, receptacle bag, tubing set, and blood containers, among other soft goods to read on "blood component collection kit.").

Examiner has noted insofar as claim 24 recites "includes a blood component collection solution, or a blood component collection transfer pack" a blood component collection kit has been recited.

24. As per claim 25, Fletcher discloses the system of claim 8, wherein the blood component collection kit inventory data is modified in response to the receipt of the blood component collection kit identifier transmitted from the interface **(Fletcher: par. [0022], [0084], [0125] and [0166]; Figs. 2A-6M)**.

25. As per claim 26, Fletcher discloses the system of claim 25, wherein the system computer generates a notification when the blood component collection kit inventory data is modified to a value which is lower than a predetermined value **(Fletcher: par. [0314])** (Examiner considers

blood component collection solutions (e.g., plasma solutions, red blood cell solutions, etc.) to read on "blood component soft good."

26. As per claim 27, Fletcher discloses the of claim 26, wherein the notification comprises providing a reorder option corresponding to the blood component collection kit associated with the blood component collection kit identifier **(Fletcher: par. [0195])**.

27. As per claim 28, Fletcher discloses the system of claim 27, wherein the notification is transmitted to a remote access service for restocking blood component collection kit inventory **(Fletcher: par. [0195] and [0314])**.

28. As per claim 30, Fletcher discloses the system of claim 28, wherein the blood component collection kit comprises a blood component container, a hypodermic needle, a blood component sample container, and a label **(Fletcher: par. [0022], [0071], [0192], and [0315])**.

Examiner considers a barcode (i.e., label), needle, receptacle bag (i.e., blood component container, blood component sample container), tubing set, and blood containers (i.e., sample container), among other soft goods to read on "blood component collection kit."

29. Claim 31 differs from system claim 8 by reciting "[a] computer readable medium having computer program code stored thereon..." within its preamble. As per these elements, Fletcher's system and method for managing inventory of blood component collection soft goods includes computers, data storage devices, communication devices, server systems, network systems and software applications running in conjunction with various hardware devices **(Fletcher: par. [0020], [0031], [0032] and [0057])**. As such, it is readily apparent that Fletcher's system and method for managing the inventory of blood collection soft goods is controlled by a computer program stored upon a computer-readable medium.

The remainder of claim 31 substantially repeats the same limitations of claim 8 and is therefore, rejected for the same reasons given for claim 8 above and incorporated herein.

30. Claims 32-42 substantially repeat the same limitations of claims 9-12, 14-15 and 25-28 and therefore, are rejected for the same reasons given for those claims.

31. Claim 43 differs from system claim 8 by excluding hardware and software elements, namely, "a blood component collection instrument," "a system computer being operably connected to the blood collection instrument," "the system computer running a blood component collection application," "a system database having a blood component collection soft good inventory," and "an interface being operably connected to the system computer, the interface having a quarantine field." The method merely repeats the underlying process steps of system claim 8 and thus, merely repeats the same limitations of claims 8 and is therefore, rejected for the same reasons given for claim 8 above and incorporated herein.

32. Claims 44-54 substantially repeat the same limitations of claims 9-12, 14-15 and 25-28, and therefore are rejected for the same reasons given for those claims.

Response to Arguments

33. Applicant argues that Wojcik does not disclose a system for managing inventory of blood component collection kits and for preventing the use of quarantined blood component collection kits nor does Wojcik disclose a system database having a blood component collection kit inventory and quarantine information prior to use of the blood component collection kit. Examiner disagrees. Wojcik discloses tracking the products delivered into a database into inventory (i.e. a system for managing inventory of blood component collection kits) or quarantine with reasons for hold, if it is in quarantine (i.e. preventing the use of quarantined

blood component collection kits). Examiner states that how the act of prevention is carried out is not disclosed within the claim language and therefore, in response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., how the prevention of quarantine goods) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

34. Furthermore, the terms "blood component kits" is not pointed out clearly within the claim language and therefore given the broadest reasonable interpretation.

35. Applicant should provide a reasoned statement explaining why the Applicant believes the Examiner has erred substantively as to the factual findings. A mere conclusory statement of the prior art not teaching the claimed invention is not enough; instead, there must be some articulated reasoning with some rational underpinning to support the differences between the prior art and the claimed invention stating why the reference is not modifiable even though it solves the pertinent problem.

36. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Conclusion

37. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHEETAL R. RANGREJ whose telephone number is (571) 270-1368. The examiner can normally be reached on M-F 8:30-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jerry O'Connor can be reached on (571) 272-6787. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or (571) 272-1000.

/S. R. R./
Examiner, Art Unit 3686
August 29, 2009

/Gerald J. O'Connor/
Supervisory Patent Examiner
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